ATTACHMENT G: 510K SUMMARY STATEMENT

SEP 2 1 2011

510(k) Summary of Safety and Effectiveness

The following section is included as required by the Safe Medical Device Act (SMDA) of 1990.

Date Prepared: June 3, 2011
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510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:

Trade Name:	Triple Lumen PFM PICC
Common Name:	Catheter, Intravascular, Therapeutic, Long Term
Classification:	LJS
Equivalent Devices:	
Manufacturer:	PFM Medical
Name:	PFM PICC
510(k) #:	K083873
Manufacturer:	CR Bard
Name:	POWERPICC, POLY PER-Q-CATH, 6FR TL POLY PER-Q-CATH, POWER HOHN, AND POWER LINE
510(k) #:	K071875

Device Description:
The Triple Lumen PFM PICC is a 6F triple lumen peripherally inserted central venous catheter designed to perform infusion, intravenous therapy, blood sampling and also power injection of contrast media studies.

The catheter is made of radiopaque polyurethane tubing are inserted peripherally. Each Triple Lumen PFM PICC has a kink resistant, reverse tapered catheter design. The Triple Lumen PFM PICC kit includes a catheter and introduction components. The catheter is supplied sterile and non-pyrogenic in a variety of kit configurations.

The Triple Lumen PFM PICC is indicated for dwell times shorter or greater than 30 days. The Triple Lumen PFM PICC can be used for venous pressure monitoring. The Triple Lumen PFM PICC catheter assembly has been tested to withstand power injection of worst-case viscosity injection media at 5 ml/sec with a maximum power injector pressure of 300 psi.

The fully assembled Triple Lumen PFM PICC consists of an extruded triple lumen polyurethane catheter insert molded into an injection-molded polyurethane hub (having integral suture tabs) that has extension leg tubing bonded to ISO standard Luer lock fittings for access attachment.

The primary lumen is power injectable. The purple extension leg tubing from the hub has the words 'Power Injectable' and the gauge size printed on the tubing. The clamp ID ring on this extension states '5ml/sec max' and 'Check Blood Return and Flush'. The two non-power injectable lumens are equivalent in size, but smaller than the power injectable lumen. The extension tubing legs are clear. The clamp ID ring on these extensions state "**DO NOT** POWER INJECT" on one side and the gauge size printed on the other.

The catheter has depth indicating markings to assist in depth of insertion into the peripherally accessed vein. The device has no components made of natural rubber latex.

Intended Use:
The Triple Lumen PFM PICC (CT Rated and Non-Rated) is indicated for short or long term peripheral access to the central venous system for infusion, intravenous therapy, blood sampling and power injection of contrast media.

The Triple Lumen PFM PICC has a maximum recommended infusion rating of 5 ml/sec.

The primary line of the Triple Lumen PFM PICC is also indicated for central venous pressure monitoring. For central venous pressure monitoring, it is recommended that a catheter of lumen of 20 gauge or larger be used.

Technical Characteristics
The Triple Lumen PFM PICC has equivalent technological characteristics with respect to the basic catheter design and function of the predicate PFM PICC (SE-K083873) and the CR Bard PowerPICC (SE-K071875) catheters. The Triple Lumen PFM PICC's power injection capabilities are comparable to the predicate PFM PICC and the CR Bard PowerPICC catheters. Differences do not raise any new questions regarding safety and effectiveness.

Safety and Performance Tests
Performance testing of the Triple Lumen PFM PICC was conducted in accordance with the following international standards:

- Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, March 16, 1995
- ISO 10555-1:2009, Sterile, single-use intravascular catheters, Part 1. General requirements
- BS/EN/ISO 10555-3 -1996/Cor 1:2002, Sterile, single-use intravascular catheters, Part 3. Central venous catheters
- AAMI/ANSI/ISO 10993-1:2009, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, and the FDA Modified Safety & ISO 10993 Test Profile
- AAMI/ANSI/ISO 1 0993-7:-2008, Biological Evaluation of Medical Devices Part 7: Ethylene Oxide Sterilization Results
- AAMI/ANSI/ISO 11135:2007, Sterilization of Healthcare Products Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 14971:2007, Medical Devices - Risk Management for Medical Devices.

The Triple Lumen PFM PICC met all established acceptance criteria. Verification and Validation testing conducted on the Triple Lumen PFM PICC yielded acceptable results. Risk Management analysis did not identify any new types of safety or efficacy questions for the Triple Lumen PFM PICC

The results of these tests, in conjunction with the substantial equivalence claims effectively demonstrate that the Triple Lumen PFM PICC is substantially equivalent to the cited predicate devices.

Summary of Substantial Equivalence
Based on the indications for use and safety and performance testing, the Triple Lumen PFM PICC meets the requirements that are considered for its intended use and is substantially equivalent in design materials, sterilization, and indications for use to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Salvadore F. Palomares
Director of Regulatory Affairs
PFM Medical, Incorporated
1815 Aston Avenue, Suite 106
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SEP 2 1 2011

Re: K110914
Trade/Device Name: Triple Lumen PFM PICC
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous Implanted Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: July 26, 2011
Received: July 27, 2011

Dear Mr. Palomares:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k): K110914

Device Name: **Triple Lumen PFM PICC**

Indications for Use: The Triple Lumen PFM PICC (CT Rated and Non-Rated) is indicated for short or long term peripheral access to the central venous system for infusion, intravenous therapy, blood sampling and power injection of contrast media.

The Triple Lumen PFM PICC has a maximum recommended infusion rating of 5 ml/sec.

The primary line of the Triple Lumen PFM PICC is also indicated for central venous pressure monitoring. For central venous pressure monitoring, it is recommended that a catheter of lumen of 20 gauge or larger be used.

Prescription Use ___X_____ AND/OR Over the Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

RH C. Chyn

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110914